



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,036	11/20/2000	Hortense W. Dodo	077281-0104	6841

22428 7590 02/20/2004

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

GIBBS, TERRA C

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,036

Applicant(s)

DODO ET AL.

Examiner

Terra C. Gibbs

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 19, 2003 has been entered.

Claims 1-28 are pending in the instant application. Claims 1-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on October 8, 2002. New claims 27 and 28 are acknowledged.

Claims 21-28 have been examined on the merits.

Response to Amendment

Applicants Amendment filed December 4, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed June 4, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification does not provide sufficient written description of an adequate number of species of peanut allergen genes. The specification does not define the term “peanut allergen gene”. When the claims are analyzed in light of the specification, the instant invention encompasses any peanut allergen gene. However, the specification at pages 20 and 21, lines 5-30, and 1-5, respectively, discloses only the *Ara h* allergen gene family. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, the *Ara h* allergen gene is the only species whose complete structure is disclosed.

Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics, specific features, and functional attributes that would distinguish different members of the claimed genus. In the instant case, there are no other identifying characteristics, specific features, or functional attributes of a peanut allergen gene. Therefore, the specification as filed, does not provide

Art Unit: 1635

sufficient description that would allow one of skill in the art to use the *Ara h* allergen gene family to predict the structures of any/all peanut allergen genes.

The specification provides insufficient written description to support the genus encompassed by the claims. The skilled artisan would not be able to envision the structure of the genus of peanut allergen genes, based on the small number of species disclosed in the specification and the prior art, because the structures of such compounds are highly variant (e.g. nucleic acid sequence).

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry,

Art Unit: 1635

whatever is now claimed.” (see page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invention what is claimed.” (See Vas-Cath at page 1116).

Therefore, in order to meet the written description requirement according to the full scope of the claimed invention, applicant must provide a description of peanut allergen genes, according to the broadest reasonable interpretation given to the claimed invention. The specification does not define peanut allergen genes, and only the *Ara h* allergen gene family has been described and therefore reduced to practice. The specification fails to teach the chemical or physical structures of other peanut allergen genes, or the common attributes of the genus of allergen genes.

Therefore, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph. The species specifically disclosed is not representative of the genus because the genus is highly variant. In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of peanut allergen genes. Therefore, only the embodiments of the invention reduced to practice in the examples meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. (See page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21, 22, 23, 25, 26, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tada et al. (FEBS Letters, 1996 Vol. 391:341-345) in view of Kleber-Janke et al. (Allergy and Immunology, 1999 Vol. 119:265-274), and Lacorte et al. (Plant Cell Reports, 1991 Vol. 10:354-357).

Claim 21 is drawn to a method for producing a transgenic peanut plant with reduced or undetectable allergen protein content in the seed, comprising identifying a homologous region common to more than one *Ara h* allergen gene; cloning the homologous region in a vector modified for peanut transformation; transforming a recipient peanut plant cell with the vector; and identifying a transgenic plant that produces seeds having reduced or undetectable allergen protein content. Claims 22, 23, 25 and 26 are dependent on claim 21 and include all the

Art Unit: 1635

limitations of claim 21, with the further limitations, wherein said *Ara h* allergen gene is selected from the group consisting of *Ara h1*, *Ara h2*, *Ara h3*, *Ara h4*, *Ara h5*, *Ara h6* and *Ara h7*; wherein said recipient peanut cell is transformed by *Agrobacterium*-mediated method of transformation; wherein said promoter is selected from the group consisting of constitutive, inducible, and tissue-preferred and wherein said promoter is a seed-preferred promoter. Claim 27 is drawn to a method for producing a transgenic peanut plant with reduced or undetectable allergen protein content in the seed comprising identifying a homologous region common to more than one peanut allergen gene, wherein said allergen gene can induce an allergic reaction in humans; cloning the homologous region in a vector modified for peanut transformation, wherein the homologous region is operably linked to a promoter; transforming a recipient peanut plant cell with the vector; and identifying a regenerated fertile transgenic peanut plant that produces seeds having reduced or undetectable allergen protein content. Claim 28 is dependent on claim 27 and includes all the limitation of claim 27, with the further limitation, wherein said peanut plant is selected from cultivars 'Florunner', 'New Mexico Valencia', Georgia Green', and Georgia Red'.

Tada et al. teach a cloned gene encoding the 16-dKa allergenic protein from rice was operably linked to a promoter, cloned in a vector in the antisense orientation and transformed by electroporation in rice seeds (see page 341, second column). Tada et al. further teach the level of the 16-kDa protein was significantly reduced in the rice seed in a number of the progeny following transformation using the antisense approach (see Figures 3 and 4). Tada et al. further teach that this antisense approach could be used in other crops containing known allergens, to selectively reduce or eliminate the levels of specific allergenic proteins (see page 181, last

Art Unit: 1635

paragraph). Specifically, Tada et al. teach “Antisense RNA with a complementary sequence of mRNA has been used experimentally to inhibit gene expression in bacteria, yeast, plant and animal cells and the antisense strategy has also been reported to be practically applicable to transgenic crop plants to which genes that produce antisense RNA are introduced to suppress the gene expression” (see page 341, first column last line and second column, first 4 lines). Tada et al. also teach constitutive and seed-preferred promoters were used to for antisense gene expression in rice plants (see page 391, second column and page 344, second to last paragraph).

Tada et al. do not teach an *Ara h* allergen gene or a method of identifying a homologous region common to more than one *Ara h* allergen gene or peanut transformation using the *Agrobacterium*-mediated method of transformation.

Kleber-Janke et al. teach the *Ara h* gene family as highly allergenic glycoproteins in peanut. Kleber-Janke et al. teach the isolation of a panel of peanut allergen genes common to the *Ara h* gene family. Kleber-Janke et al. teach the identification of homologous regions common to more than one *Ara h* allergen gene. Kleber-Janke et al. teach the alignment of the deduced amino acid sequences of *Ara h*2, h6, and h7 shows the identical regions of these three members of the *Ara h* gene family (see Figure 3).

Lacorte et al. teach gene transfer into peanut plants via *Agrobacterium tumefaciens* is an efficient way to introduce desirable traits into crop plants (see Figure 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the transgenic rice plant with reduced allergen protein content in the seed of Tada et al. to produce a transgenic peanut plant with reduced or undetectable allergen protein content in the seed of the instant invention. One of ordinary skill would have been motivated to

Art Unit: 1635

substitute the transgenic rice plant with a transgenic peanut plant since one of skill in the art would have desired to make a transgenic peanut plant with reduced allergen protein content in the seed to prevent allergic reactions in sensitized individuals. Tada et al. taught the production of transgenic rice plants with a reduced 16-kDa allergen protein in the seed using an antisense approach. Further, Tada et al. taught the antisense approach could be used on other crops to silence allergen protein content in the seed. One of ordinary skill in the art would have been motivated to substitute the 16-kDa allergen protein with an *Ara h* allergen gene because the art taught that both genes are major dietary allergens in rice grain and peanut grain, respectively (Kleber-Janke et al.).

It would have been obvious to one of ordinary skill in the art to identify a homologous region common to more than one *Ara h* allergen gene because Kleber-Janke et al. taught the identity of similarities between allergens can determine the frequency recognition of IgE serum binding in peanut-sensitive patients, which is important in allergy sensitivity in individuals. One of ordinary skill in the art would have expected to be successful in identifying a homologous region common to more than one *Ara h* allergen gene since the prior art explicitly taught such techniques by aligning the deduced amino acid sequences of the *Ara h* gene family (Kleber-Janke et al.). Additionally, it would have been obvious to one of ordinary skill in the art to identify the homologous region, link it to a promoter and clone it into a vector since Tada et al. taught such methods could silence endogenous genes in plants. One of ordinary skill in the art would have expected to be successful in cloning the promoter-linked homologous region in a vector and transforming a cell with that vector since Tada et al. taught such methods would successfully reduce allergen protein content in seeds. One of ordinary skill in the art would have

Art Unit: 1635

expected success in the transforming the peanut using the *Agrobacterium*-mediated method of transformation since Lacorte et al. taught gene transfer into peanut plants via *Agrobacterium tumefaciens* is an efficient way to introduce desirable traits into crop plants. Regarding claim 28, and the use of peanut cultivars Florunner', 'New Mexico Valencia', Georgia Green', and Georgia Red'. These peanut cultivars are normal oil chemistry peanut cultivars (as evidenced by Krapovickas, A (Domestication and exploitation of plants and animals. London: Gerald Duckworth, 1969:247) and one of skill in the art would have been motivated to use any one of these peanut cultivars as they are commonly processed, consumed and used for breeding.

The invention as a whole would therefore have been obvious to one of ordinary skill in the art at the time the invention was made.

Claims 21, 22, 24, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tada et al. (FEBS Letters, 1996 Vol. 391:341-345) and Kleber-Janke et al. (Allergy and Immunology, 1999 Vol. 119:265-274) as applied to claims 21, 22, 23, 25 and 26 above and further view of Klein et al. (Nature, 1987 Vol. 327:70-73).

Claims 21, 22, 24, 25 and 26 are described in the 103(a) rejection against claims 21, 22, 23, 25 and 26 above. Claim 24 is dependent on claim 21 and includes all the limitations of claim 21, with the further limitation, wherein said recipient peanut cell is transformed by the biolistic method.

Tada et al. and Kleber-Janke et al. are relied upon as cited in the 103(a) rejection against claims 21, 22, 23, 25 and 26 above.

Art Unit: 1635

Tada et al. do not teach peanut transformation using the biolistic method of transformation.

Klein teach introducing nucleic acids into a plant cell using high velocity biolistic penetration by small particles is an alternative approach to the restricted *Agrobacterium tumefaciens* transformation method (see Table 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Tada et al. to produce a transgenic peanut plant with reduced or undetectable allergen protein content in the seed with a reasonable expectation of success since Tada et al. taught the production of transgenic rice plants with a reduced 16-kDa allergen protein in the seed. One of ordinary skill would have been motivated to substitute the transgenic rice plant with a transgenic peanut plant since Tada et al. taught the approach could be used on other crops. One of ordinary skill in the art would have been motivated to substitute the 16-kDa allergen protein with an *Ara h* allergen gene because the art taught that both genes are major dietary allergens in rice grain and peanut grain, respectively (recognized by more than 90% of the peanut-allergic patients) (Kleber-Janke et al.).

It would have been obvious to one of ordinary skill in the art to identify a homologous region common to more than one *Ara h* allergen gene because Kleber-Janke et al. taught the identity of similarities between allergens can determine the frequency recognition of IgE serum binding in peanut-sensitive patients. One of ordinary skill in the art would have expected to be successful in identifying a homologous region common to more than one *Ara h* allergen gene since the prior art explicitly taught such techniques by aligning the deduced amino acid sequences (Kleber-Janke et al.). Additionally, it would have been obvious to one of ordinary

Art Unit: 1635

skill in the art to identify the homologous region, link it to a promoter and clone it into a vector since Tada et al. taught such methods could silence endogenous genes in plants. One of ordinary skill in the art would have expected to be successful in cloning the promoter-linked homologous region in a vector and transforming a cell with that vector since Tada et al. taught such methods would successfully reduce allergen protein content in seeds. One of ordinary skill in the art would have expected success in the transforming the peanut using high velocity biolistic method of transformation since Klein et al. taught gene transfer into peanut plants via the high velocity biolistic method is an alternative approach to introduce desirable traits into crop plants.

The invention as a whole would therefore have been obvious to one of ordinary skill in the art at the time the invention was made.

Response to Remarks

Applicant's remarks to the Final Office Action, filed December 4, 2003 are acknowledged. Applicants argue that the reasons made of record fail to establish a reason for combining the cited art and the combination of references do not render the present invention obvious. Applicants argue that in order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to combine reference teachings. Applicants argue that the combination of references do not render the present invention obvious. More specifically, Applicants argue that Neither Tada et al. nor Kleber-Janke et al., alone or together, teach or even suggest identifying a region homologous to more than one *Ara h* gene and then cloning the homologous *Ara h* region in the antisense orientation for peanut transformation. Applicants argue that Tada et al. disclose, "14-16 kDa allergens are multigene products" and "more than 10

Art Unit: 1635

homologous cDNA clones encoding the 14-16 kDa allergens have been identified". However, Applicants argue that Tada et al. neither teaches nor suggests identifying a region homologous to more than one allergen for cloning in the antisense orientation. Applicants argue that furthermore, Kleber-Janke et al. neither teaches nor suggests identifying a region homologous to more than one *Ara h* gene and transforming a peanut with an antisense *Ara h* construct. Applicants argue that while Kleber-Janke et al. may have identified regions homologous to more than one *Ara h* gene, nowhere does the reference discuss transforming a peanut plant with an antisense *Ara h* gene, let alone a region homologous to more than one *Ara h* gene. Applicants contend that the combination of the references would not render the instant invention obvious. Applicants argue that while Tada et al. may use antisense technology for reducing 14-16 kDa proteins in rice, neither Tada et al. nor Kleber-Janke et al. disclose a method for producing a transgenic peanut plant with reduced allergen content in the seed. Applicants argue that at best, Tada et al. discloses that antisense may be applicable to crop plants, but the disclosure of a genus does not necessarily render each species within that genus *prima facie* obvious. Applicants argue that the genus of crop plants is too large to inherently describe every member within it. Applicants contend that Tada et al. fail to identify any crop plant and therefore cannot provide a motivation to select any particular species.

Applicant's arguments have been fully considered, but are not found persuasive. Applicants argue against the references individually, but must consider the rejection based upon the combination of the references. *See*, MPEP 2145. As stated in the previous Office Action, Tada et al. teach a method for antisense suppression of a 16 kDa allergen in rice seeds by operably linking a fragment of the cDNA encoding the rice allergen in the antisense orientation

Art Unit: 1635

and cloning the fusion construct into a vector for rice transformation. Tada et al. further teach the level of the 16-kDa allergen protein was significantly reduced in the rice seed in a number of the progeny following transformation. Tada et al. further teach "Antisense RNA with a complementary sequence of mRNA has been used experimentally to inhibit gene expression in bacteria, yeast, plant and animal cells and the antisense strategy has also been reported to be practically applicable to transgenic crop plants" (see page 341, first column last line and second column, first 4 lines). Therefore, and as stated in the previous Office Action, it would have been obvious to one of ordinary skill in the art to devise a method for producing a transgenic peanut plant with reduced or undetectable allergen protein content in the seed using the method of Tada et al. As stated in the previous Office Action, since Tada et al. teach antisense methodologies in a rice plant, it would have been obvious to one of ordinary skill in the art to substitute the rice plant with a peanut plant since Tada et al. taught the antisense approach could be used on other crops. As stated in the previous Office Action, it would have been obvious to one of ordinary skill in the art to reduce the *Ara h* allergen gene in a peanut plant since the art has asserted that the *Ara h* gene family are major dietary allergens in peanut grain (recognized by more than 90% of the peanut-allergic patients). As stated in the previous Office Action, one of ordinary skill in the art would have expected to be successful in identifying a homologous region common to more than one *Ara h* allergen gene since the prior art explicitly taught such techniques by aligning the deduced amino acid sequences of several *Ara h* genes (Kleber-Janke et al.). It is noted that Kleber-Janke et al. identify several homologous regions common between *Ara h2*, *Ara h6* and *Ara h7* (see Figure 3). Based on the teachings of Kleber-Janke et al., an artisan would have been able to determine homologous regions among any *Ara h* gene. Therefore, using the

Art Unit: 1635

combined methods of Tada et al. and Kleber-Janke et al., one of ordinary skill would have been motivated and expected success in devising a method for identifying a region homologous to more than one *Ara h* gene and transforming a peanut plant with an antisense *Ara h* homologous region.

Applicants also argue that an obviousness rejection cannot be based upon unqualified hindsight reasoning. Applicants contend that the Examiner has not established a motivation or desirability for combining the teachings of the references, but has merely used Applicants' specification as a hindsight road map to recreate the claimed invention. Applicants argue that in summary, none of the cited references, alone or together, disclose a method for identifying a region homologous to more than one *Ara h* gene and transforming a peanut plant with an antisense *Ara h* homologous region and therefore no *prima facie* case of obviousness is established.

Applicant's arguments have been fully considered, but are not found persuasive. In response to applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Therefore, at the time of filing, a method for identifying a region homologous to more than one *Ara h* gene was well known (see Kleber-Janke et al.). Additionally, producing a transgenic peanut plant with reduced allergen protein content in the

Art Unit: 1635

seed was obvious in the art at the time of filing as taught by the suggestion and motivation of Tada et al. to use the antisense approach in other crops containing known allergens, to selectively reduce or eliminate the levels of specific allergenic proteins. Therefore, given the teachings of Tada et al. and Kleber-Janke et al. a *prima facie* case of obviousness has been established.

Conclusions


No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (571) 272-0758. The Examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg
February 17, 2004


KAREN A. LACOURCIERE, PH.D.
PRIMARY EXAMINER